K001935

AUG 22 2000

BECKMAN COULTER

510(k) Summary

Prepared August 17, 2000

Applicant's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Contact Person: Jan Olsen

Device Name

Trade Name - Access® Testosterone Reagents on the Access® Immunoassay Systems
Common Name – Testosterone Enzyme Immunoassay
Classification name – Testosterone Test System (21 CFR 1680)

Predicate Device

Coat-A-Count™ Total Testosterone
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, CA 90045-5597 USA

510(k) Number: K813401

Device Description

The Access® Testosterone reagents and the Access® Immunoassay Analyzer comprise the Access® Immunoassay System for the quantitative determination of testosterone in human serum.

Intended Use

The Access® Testosterone assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total testosterone levels in human serum and plasma, using the Access® Immunoassay Systems.

Comparison of Technological Characteristics

Both the Access® Testosterone Immunoassay and the DPC Coat-A-Count™ Total Testosterone assay quantitatively measure serum testosterone by means of competitive immuno/radioimmunoassays utilizing the competition between testosterone in the patient sample and conjugated testosterone tracer for a limited amount of anti-testosterone antibody.

The Access® Testosterone immunoassay measures testosterone using an automated system with paramagnetic particle solid phase technology and chemiluminescent signal detection. The DPC Coat-A-Count™ Total Testosterone radioimmunoassay measures testosterone using a solid phase technology and ^{125}I-labeled antibody detection.

The Access® Testosterone immunoassay utilizes an alkaline phosphatase conjugated testosterone tracer with a monoclonal anti-testosterone antibody and a goat anti-mouse coated paramagnetic particle, while the DPC Coat-A-Count™ Total Testosterone radioimmunoassay utilizes an ^{125}I-labeled polyclonal antibody coated polypropylene tube.

Summary of Studies

Correlation: A comparison of testosterone values from 345 samples, ranging from 0.11 to 14.81 ng/ml, run with both the ACCESS® Testosterone Immunoassay and the DPC Coat-A-Count™ Total Testosterone radioimmunoassay demonstrated good agreement with the following statistical data: $r = 0.982$; $y = 0.951x + 0.175$.

Recovery: Linearity studies performed by diluting fifty two human serum samples 1:2 with Access® Testosterone Zero Calibrator provided an average recovery of 105%, with individual recoveries ranging from 96 to 116%.

Precision: Intra-assay imprecision ranged from 1.50% CV to 3.93% CV. Inter-assay imprecision ranged from 2.98% CV to 7.08% CV.

Specificity: There was no significant interference from therapeutic drugs or compounds similar to testosterone. In addition, there was no significant interference from potential sample contaminants (total protein, bilirubin, hemoglobin, and triglycerides),

Analytical Sensitivity: The lowest detectable level of testosterone distinguishable from zero (Access® Testosterone Calibrator S0) with 95% confidence is 0.084 ng/ml.

Conclusion

The Access® Testosterone immunoassay reagents, when used in conjunction with the Access® Immunoassay Analyzer, are substantially equivalent to the DPC Coat-A-Count™ Total Testosterone test system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 22 2000

Ms. Jan Olsen
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K001935
Trade Name: Access® Testosterone Reagents on the Access® Immunoassay Systems
Regulatory Class: I Reserved
II
Product Code: CDZ
JIS
Dated: June 23, 2000
Received: June 26, 2000

Dear Ms. Olsen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Access® Testosterone

Indications For Use:

The Access® Testosterone assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total testosterone levels in human serum and plasma, using the Access® Immunoassay Systems. Measurement of testosterone is used in the diagnosis and treatment of disorder involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrenogenital syndromes.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K001935

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)